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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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08/452,659 05/25/95 FIERO

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EXAMINER

MARTINELLI, J

18N2/0116

ART UNIT

PAPER NUMBER

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1804

DATE MAILED: 01/16/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 7/20/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☒ Suggestion for Deposition of Biological Material

Part II SUMMARY OF ACTION

- ☒ Claims 31-34 are pending in the application.
Of the above, claims — are withdrawn from consideration.
- ☒ Claims 1-30 have been cancelled.
- ☐ Claims — are allowed.
- ☒ Claims 31-34 are rejected.
- ☐ Claims — are objected to.
- ☐ Claims — are subject to restriction or election requirement.
- ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on —. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on —, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed —, has been ☐ approved; ☐ disapproved (see explanation).
- ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☒ been filed in parent application, serial no. 06/250,409; filed on 4/2/87.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

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This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claims 31-34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite.

- (a) The recitation of "with which it is normally associated" (claims 31 and 32) is vague and indefinite because the application does not mention what these proteins may be. Thus, the metes and bounds of the claims are not clear.
- (b) The recitation of "characterized by" (claim 31) is vague and indefinite because it is not clear whether the DNA actually possesses the listed properties.
- (c) The recitation of "characterized in that" (claim 32) is vague and indefinite because it is not clear whether the DNA actually possesses the listed properties.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure. It is not evident that the deposited biological materials

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mentioned in the claims are permanently available to the public. A "Suggestion for Deposit of Biological Material" is attached to this Office action.

Claims 31-34 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure. The instant application does not disclose what amounts of human IFN- β 1 may or may not be effective in a therapeutic method of tumor treatment in humans.

Claims 31-34 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the

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time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 31, 33, and 34 are rejected under 35 U.S.C. § 103 as being unpatentable over Taniguchi et al (Gene 10: 11 (1980)) in view of Roberts et al (Proc. Natl. Acad. Sci. USA 76: 5596 (1979) and further in view of Borden (Annals of Internal Medicine 91: 472 (1979)). Taniguchi et al teaches the molecular cloning of the human IFN- β 1 gene. Roberts et al teaches the expression of a eukaryotic gene in an E. coli host cell using an expression vector. Borden suggests the use of human fibroblast interferon (i.e. β interferon) in anti-tumor therapy. It would have been obvious to one of ordinary skill in the art at the time the invention was made to express the human IFN- β 1 gene of Taniguchi et al in the manner of Roberts et al in order to produce large amounts of human IFN- β 1 for anti-tumor therapy as suggested by Borden.

Claims 32-34 are rejected under 35 U.S.C. § 103 as being unpatentable over Knight et al (Science 207: 526 (1980)) in view of Borden. Knight et al teaches the isolation and purification of human IFN- β 1 interferon (the amino terminal end of the interferon of Knight et al is the same as the amino terminal end of the interferon mentioned in the claims). Borden suggests the use of human fibroblast interferon (i.e. β interferon) in anti-tumor therapy. It would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate human IFN- β 1 in the manner of Knight et al and to use that human IFN- β 1 for anti-tumor therapy as suggested by Borden.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Art Unit 1804 at (703) 305-3014. The
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faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1804.


JAMES MARTINELL, PH.D.
SENIOR LEVEL EXAMINER
GROUP 1800